

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**IN RE NEW ENGLAND COMPOUNDING)
PHARMACY, INC. PRODUCTS)
LIABILITY LITIGATION)**

_____)

THIS DOCUMENT RELATES TO:)

**Those Suits Identified in the Exhibit 1 (Doc.)
770-1) to the Tennessee Defendants' Motion to)
Dismiss)**

_____)

MDL No. 2419

Dkt. No. 1:13-md-2419 (RWZ)

**PLAINTIFFS' STEERING COMMITTEE'S RESPONSE IN OPPOSITION TO THE
TENNESSEE DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' COMPLAINTS
FOR FAILURE TO COMPLY WITH TENN. CODE ANN. § 29-26-121 (DOC. 770)**

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The Plaintiffs' Steering Committee ("PSC") respectfully submits this response opposing the Tennessee Defendants' Motion to Dismiss for Failure to Comply with Tenn. Code Ann. § 29-26-121 (Doc. 770, the "Motion").¹

I. Procedural Background

Because the present Motion raised issues the PSC maintained were case-specific, the parties met and conferred in an attempt to identify the "global" issues raised by the Motion that are appropriate for resolution now and the case-specific issues that should be held in abeyance. As a result of that meet and confer, the parties agreed that the following issue included in the present Motion should be briefed and argued at this stage of the proceedings:

- (1) Whether plaintiffs were required to (a) identify Barry Cadden, NECC, and other affiliated parties in the notice of intent to the clinic defendants as health care providers that would be named defendants and (b) provide a HIPAA release allowing clinic defendants to obtain records pre-suit from Barry Cadden, NECC, and other affiliated defendants pursuant to Tenn. Code Ann. § 29-26-121.²

In addition to that issue, the PSC asserts that an additional "global issue" raised in the Defendants' motions should likewise be addressed:

¹ For purposes of this Response, the term "Tennessee Defendants" shall refer to those defendants who filed the relevant Motion to Dismiss (Doc. No. 770 and the memorandum in support thereof, Doc. No. 898) and include the following defendants: Saint Thomas Outpatient Neurosurgical Center, LLC ("Saint Thomas Clinic"), Howell Allen Clinic, a Professional Corporation, and part owner of Saint Thomas Clinic ("Howell Allen"), John W. Culclasure, M.D., the Medical Director of Saint Thomas Clinic ("Dr. Culclasure"), Debra V. Schamberg, R.N., the Facilities Director of Saint Thomas Clinic ("Ms. Schamberg"), Specialty Surgery Center, Crossville, PLLC, another clinic in Tennessee and unrelated to Saint Thomas Clinic ("SSC"), Kenneth R. Lister, M.D., the Medical Director of SSC ("Lister"), and Kenneth Lister, M.D., P.C., the incorporated entity for Lister's practice ("Dr. Lister's Practice").

² See Doc. Nos. 1100 and 1100-1. Two additional "global" issues have been identified by the parties. Those two issues are briefed separately (*see* Doc. 1115) in response to the Saint Thomas Entities Motion to Dismiss. Plaintiffs rely upon and incorporate that brief herein by reference.

Whether the claims of certain plaintiffs should be dismissed because their middle names were not included in pre-suit notice letters notifying the Defendants of plaintiffs' intent to file suit.

The parties have further agreed that all other issues raised by the Motion should be resolved at a later point in the proceedings.³

II. Facts Supporting Plaintiffs' Claims

The facts supporting the Tennessee Plaintiffs' claims are discussed at length in the Tennessee Plaintiffs' Response in Opposition to the Tennessee Defendants' Motion to Dismiss Global Claims.⁴ Those facts are incorporated herein by reference and need not be repeated in this filing.

III. ARGUMENT

Tenn. Code Ann. § 29-26-121 is in derogation of the common law. The common law does not contain the technical requirements found in Tenn. Code Ann. § 29-26-121. Therefore, the derogatory effect of those technical requirements upon the common law rights of injured tort victims must be strictly and narrowly construed.⁵ Stated another way, "[t]he common law may not be altered any further by statute than the statute expressly declares..."⁶ Under Tennessee law, trial courts should be "reluctant to give effect to rules of procedure which seem harsh and unfair, and which prevent a litigant from having a claim adjudicated upon its merits."⁷

³ *Id.*

⁴ Doc. 1040.

⁵ *Cardwell v. Bechtol*, 724 S.W.2d 739, 744 (Tenn. 1987); *Steele v. Ft. Sanders Anesthesia Group, P.C.*, 897 S.W.2d 270, 282 (Tenn.Ct.App. 1994).

⁶ *Steele*, 897 S.W.2d at 282.

⁷ *Childress v. Bennett*, 816 S.W.2d 314, 316 (Tenn.1991).

A. Plaintiffs Were Not Required to List NECC, Ameridose and Barry Cadden In Pre-suit Notices Required by the Tennessee Healthcare Liability Act Because Plaintiffs' Claims Against Those Parties Are Product Liability Claims, Not Health Care Liability Actions.

The Tennessee Defendants incorrectly seek dismissal of hundreds of cases against them on the specious and unsupported grounds that Plaintiffs were required to identify certain NECC-related defendants in the pre-suit notices sent to the Tennessee Defendants pursuant to Tenn. Code Ann. § 29-26-121.⁸ In support of that position, the Tennessee Defendants make the inaccurate assertion that all claims in all Tennessee lawsuits are “health care liability actions.”⁹ The Defendants make that assertion even though none of the Tennessee Plaintiffs assert health care liability actions against the product manufacturer, New England Compounding Pharmacy, Inc., d/b/a New England Compounding Center (“NECC”), and its affiliates Barry Cadden and Ameridose (hereinafter collectively “NECC Defendants”). The Tennessee Plaintiffs plead product liability claims against NECC and its affiliates, not health care liability actions. Therefore, the Tennessee Plaintiffs were not required to list NECC, Cadden and Ameridose in any pre-suit notices required by the Tennessee Healthcare Liability Act.

When the NECC Defendants mass produced contaminated steroids and distributed those steroids in bulk across the country, they were not acting as health care providers. They were acting as drug manufacturers. The Tennessee Defendants acknowledge that obvious fact in their Memorandum in Support of Their Motion to Dismiss Global Claims which states:

⁸ In relevant part, Tenn. Code Ann. § 29-26-121(a) states that “[a]ny person...asserting a potential claim for health care liability shall give written notice of the potential claim to each health care provider that will be a named defendant at least sixty (60) days before the filing of a complaint based upon health care liability in any court of this state.” Subsection (2) goes on to state that the notice shall contain “a list of the name and address of all providers being sent a notice; and a HIPAA compliant medical authorization permitting the provider receiving the notice to obtain complete medical records from each other provider being sent a notice.” Tenn. Code Ann. § 29-26-121(a)(2)(D) and (E).

⁹ (Defendants’ Memorandum, Doc. 898, pp. 4 and 7).

With no concern for individual patients, and no regard for scores of health care providers across the United States, NECC manufactured and distributed contaminated MPA.¹⁰

In addition to that express acknowledgment, the Tennessee Defendants' conduct likewise acknowledged that NECC acted as a product manufacturer, and not a healthcare provider, when it made and distributed compounded steroids in bulk to pain clinics in Tennessee. Shortly after news of the fungal meningitis outbreak became public, the defendant Saint Thomas Clinic sent a letter to NECC asserting breach of warranty claims against that product manufacturer. (*See Exhibit 1 attached*). In other words, Saint Thomas Clinic treated NECC like a manufacturer of defective "goods," and it asserted that those goods failed to satisfy the implied statutory warranties of merchantability and fitness.¹¹ Saint Thomas Clinic did not treat NECC like a healthcare provider who provided pharmacy compounding services, and it did not threaten to pursue healthcare liability claims against NECC.¹²

The fact that the NECC Defendants were acting as drug manufacturers, rather than pharmacies or pharmacists, is further evidenced by the fact that they did not abide by Massachusetts pharmacy laws requiring individual prescriptions before compounding medications.¹³ Instead, the NECC Defendants shipped steroids in bulk across the country without requiring individual prescriptions. Therefore, the NECC Defendants had no provider/patient relationship with the Tennessee Plaintiffs, and the Tennessee Plaintiffs had no idea that a so-called pharmacy was involved in their care.

¹⁰ Doc. 772, p. 9.

¹¹ *See Exhibit 1 attached.*

¹² *Id.*

¹³ The Tennessee Defendants acknowledge in their Memorandum in Support of Their Motion to Dismiss Global Claims that "MPA is a prescription drug defined by 105 CMR § 700.002(F) as a Schedule VI controlled substance." (Doc. 772, p. 59). Mass. Gen. Law c. 94C, § 17(c) states "[a] controlled substance included in Schedule III, IV, V or VI shall not be dispensed without a written or oral prescription of a practitioner." In pertinent part, Mass. Gen. Law c. 94C, § 22(a) states "a practitioner who dispenses a controlled substance by issuing a written prescription shall state on the prescription ... the name and address of the patient..." Finally, Mass. Gen. Law c. 94C, § 19(b) states "[n]o prescription shall be issued in order for a practitioner to obtain controlled substances for supplying the practitioner for the purpose of general dispensing to patients."

Before the fungal meningitis outbreak, the Tennessee Defendants treated the NECC Defendants like manufacturers rather than pharmacies/pharmacists. Even though the Tennessee Defendants knew that individual prescriptions were required by Massachusetts law, they nevertheless ordered injectable steroids in bulk from NECC without writing or sending prescriptions for those medicines. In fact, the Tennessee Defendants knowingly helped NECC avoid pharmacy laws by submitting bogus documents to NECC along with their bulk purchase orders.¹⁴

The NECC Defendants required no pre-suit health care liability notice because Plaintiffs are not suing the NECC Defendants for health care liability. They are suing the NECC Defendants for product liability pursuant to the Tennessee Products Liability Act of 1978, Tenn. Code Ann. § 29-28-101 *et seq.* It is undisputed that this statute does not contain any type of pre-suit notice requirement.

Plaintiffs do not allege that the NECC Defendants breached any standard of care or otherwise rendered any health care service negligently.¹⁵ They allege that those defendants manufactured and distributed defective and unreasonably dangerous products in the form of steroids contaminated with lethal pathogens. Therefore, the Tennessee Plaintiffs were not required to provide pre-suit notice to the NECC Defendants under the Tennessee Health Care Liability Act. Simply put, because the Tennessee Plaintiffs are not asserting “health care liability actions” against the NECC Defendants, they were not required to send a pre-suit notice to those defendants.¹⁶

¹⁴ First Amendment to Master Complaint (Document No. 832 hereinafter “First Amend. Master Compl.”), ¶ 371.

¹⁵ See, e.g., Compl. *Reed v. Ameridose, LLC, et al.*, No. 1:13-cv-12565 (D. Mass Sept. 19, 2013) [Dkt. 1] [“*Reed* Compl.”]

¹⁶ “‘Health care liability action means’ any civil action, including claims against the state or a political subdivision thereof, alleging that a health care provider or providers have caused an injury related to the provision of, or failure to provide, health care services to a person, regardless of the theory of liability on which the action is based.” Tenn. Code Ann. § 29-26-101(a)(1). As explained in greater detail below, claims arising under the products liability act are “product liability actions” as defined in Tenn. Code Ann. § 29-28-102(6). See also *Strayhorn v. Wyeth Pharma.*,

B. Under Tennessee Law, Claims Arising from Defective Pharmaceuticals Are Product Liability Claims.

Tennessee law clearly provides that claims arising from unreasonably dangerous or defective pharmaceuticals are product liability claims governed by the Products Liability Act.

The Sixth Circuit, in addressing that very issue, stated:

The Tennessee Products Liability Act governs products liability actions in Tennessee and defines product liability actions as all actions brought for or on account of personal injury, death, or property damage caused by or resulting from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning instruction, marketing, packing or labeling of any product. The TPLA also encompasses several different theories of products liability: strict liability in tort; negligence; breach of warranty, express or implied, breach of or failure to discharge a duty to warn or instruct, whether negligent or innocent; misrepresentation, concealment or nondisclosure, whether negligent or innocent; **or under any other substantive legal theory in tort or contract whatsoever.**¹⁷

The Sixth Circuit went on to hold in *Strayhorn* that “the [Products Liability Act] governs all of plaintiffs’ claims because the claims were brought for or on account of personal injury resulting from the design, warning, instruction, marketing, packaging, and labeling of [a pharmaceutical].”¹⁸ That holding is hardly isolated. The notion that claims for injuries resulting from exposure to pharmaceuticals are “product liability actions” under the Products Liability Act enjoys near universal acceptance among reviewing courts.¹⁹ Therefore, because Plaintiffs’

Inc., 737 F.3d 378, 392 (6th Cir. 2013) (discussing nature of product liability actions against pharmaceutical manufacturers for harm arising from injuries related to the use of pharmaceuticals).

¹⁷ *Strayhorn v. Wyeth Pharma., Inc.*, 737 F.3d 378, 392 (6th Cir. 2013). This is not to say that the Product Liability Act is exclusive and precludes liability based on the alternative ground of negligence of the seller when it can be proven. *Corporate Air Fleet of Tennessee, Inc. v. Gates Learjet, Inc.*, 589 F.Supp. 1076 (6th Cir. 1984). In other words, plaintiffs can simultaneously pursue claims that defendants are liable in strict liability for selling an unreasonably dangerous product and are also liable for their negligent conduct in dispensing a tainted pharmaceutical to plaintiffs.

¹⁸ *Id.*

¹⁹ See e.g., *Montgomery v. Wyeth*, 580 F.3d 455 (6th Cir. 2009) (applying Products Liability Act to personal injuries suffered from exposure to pharmaceutical); *Mathis v. Eli Lilly & Co.*, 719 F.2d 134 (6th Cir. 1983) (same); *Payne v. Novartis Pharms. Corp.*, 967 F. Supp. 2d 1223 (E.D. Tenn. 2013); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994); *Baker v. Lederle Laboratories*, 696 S.W.2d 890 (Tenn. Ct. App. 1985); and *Witherspoon v. Ciba-Geigy Corp.*, 1986 Tenn. App. LEXIS 2773 (Tenn. Ct. App. 1986).

claims against NECC, Ameridose and Barry Cadden are product liability claims, there was absolutely no reason to send those parties pre-suit notice under the Tennessee Healthcare Liability Act.²⁰

C. As Reflected by MDL Order No. 6, the NECC Affiliated Defendants Waived All State Law Pre-Suit Filing Requirements.

To the extent that the NECC Defendants required any pre-suit notice under the Tennessee Healthcare Liability Act (which they did not), the NECC Defendants expressly waived that requirement. In fact, the NECC Defendants expressly waived all state law pre-suit notice requirements, and this Honorable Court confirmed that waiver by order. In MDL Order No. 6²¹, this Honorable Court ordered as follows:

E. Waiver of Pre-suit Notice Requirements

Each of the following defendants have agreed to waive the applicability of any “state law suit requirements,” including, but not limited to, any state law or state court rule requiring: notices of intent to sue; affidavits of merit; certifications of expert review; review by any attorney, expert, tribunal and/or panel; pre-suit arbitration; or similar pre or immediate-post-suit action concerning the substantive merits of a claim. . . .

The Defendants who have waived the “state law suit requirements” are:

1. NECC;
2. Ameridose, LLC;
3. Barry J. Cadden;
4. Lisa Conigliaro Cadden;
5. Glenn A. Chin;
6. Gregory Conigliaro;
7. GDC Properties Management, LLC;
8. Medical Sales Management, Inc.;

²⁰ It is important to note that the pre-suit notice requirements of the Tennessee Healthcare Liability Act only apply to cases filed in Tennessee courts. *See* Tenn. Code Ann. § 29-26-121(a)(1). Thus, those requirements would not apply to any cases originally filed in a state other than Tennessee, such as Massachusetts.

²¹ Doc. 209.

9. Doug Conigliaro;

10. Carla Conigliaro; and

11. Alaunus Pharmaceuticals, LLC²²

Therefore, because the NECC Defendants expressly waived all state law pre-suit filing requirements, including those contained in Tenn. Code Ann. § 29-26-121, the Tennessee Defendants' motion requesting summary dismissal of the Tennessee Plaintiffs' claims because they did not provide pre-suit notice to the NECC Defendants is contrary to this Court's MDL Order No. 6 and wholly without merit. Plaintiffs were not required to send pre-suit notice to parties who expressly waived any such requirement.

D. Strict Compliance with the Various Technical Requirements of Tenn. Code Ann. § 29-26-121 is not Required, and Prejudice Must be Shown Before a Lawsuit is Dismissed.

The Tennessee Defendants make the overly broad, and thus incorrect, assertion that in the case of *Myers v. AMISUB (SFH), Inc.*, 382 S.W.3d 300 (Tenn. 2012), the Tennessee Supreme Court held that the requirements of Tenn. Code Ann. § 29-26-121 are mandatory.²³ Those Defendants also incorrectly assert: (1) that they do not have to prove prejudice in order to obtain dismissal of an injured plaintiff's complaint, and (2) that substantial compliance with the statute cannot satisfy the technical requirements of Tenn. Code Ann. § 29-26-121. The Tennessee Defendants attempt to support those incorrect assertions by citing four unpublished decisions in a footnote that have since been contradicted by the Tennessee Supreme Court.²⁴ As explained below, there are several problems with the Defendants' assertions.

First, the *Myers* Court did not state that strict compliance with the technical requirements of Tenn. Code Ann. § 29-26-121 is mandatory. Instead, the Court carefully limited its decision to hold only that, in a health care liability action, the statutory requirements that a plaintiff give

²² MDL Order No. 6 at pages 5-6.

²³ Defendants' Memorandum, Doc. 898, p. 9.

²⁴ *Id.*, p. 9, and fn 24.

pre-suit notice [per Tenn. Code Ann. § 29-26-121] and file a certificate of good faith [per Tenn. Code Ann. § 29-26-122] with a complaint are mandatory. The *Myers* Court deliberately left for another day the question of whether the technical requirements of Tenn. Code Ann. § 29-26-121 could be satisfied by substantial compliance:

*Sections 29-26-121 and 122 respectively mandate that pre-suit notice be given and that a certificate of good faith be filed. Because these requirements are mandatory, they are not subject to satisfaction by substantial compliance.... Because no pre-suit notice was given and no certificate of good faith was filed, we need not decide whether the statutes' requirements as to the content²⁵ of the notice and the certificate of good faith may be satisfied by substantial compliance.*²⁶

Second, the four unpublished decisions cited by the Tennessee Defendants are of no consequence because the Tennessee Supreme Court subsequently addressed the issue in the case of *Stevens v. Hickman Community Health Care Services, Inc., et al.*, 418 S.W.3d 547 (Tenn. 2013)(copy attached hereto as Exhibit 2). In *Stevens*, the Court made clear that: (1) substantial compliance with the technical requirements of Tenn. Code Ann. § 29-26-121 is sufficient; and (2) a complaint should not be dismissed based upon a statutory technicality unless and until a defendant shows actual prejudice. Specifically, the Court stated:

In *Myers*, we held that "[t]o determine whether the use of the word 'shall' in a statute is mandatory or merely directory, we look to see 'whether the prescribed mode of action is of the essence of the thing to be accomplished.'" (Citations omitted). As we explained in *Jones v. Profl Motorcycle Escort Serv., L.L.C.*, the touchstone of this analysis is **whether a party's procedural error resulted in actual prejudice to an opposing party**. 193 S.W.3d 564, 571 (Tenn. 2006).²⁷

A plaintiff's less-than-perfect compliance with *Tenn. Code Ann. § 29-26-121(a)(2)(E)*, however, should not **derail** a healthcare liability claim. Non-substantive errors and omissions will not always prejudice defendants by preventing them from obtaining a plaintiff's relevant medical records. Thus, **we**

²⁵ As will be discussed herein, the Defendants' present Motion addresses the content of pre-suit notice sent pursuant to Tenn. Code Ann. § 29-26-121.

²⁶ *Myers*, 382 S.W.3d at 310 (emphasis added).

²⁷ *Stevens*, 418 S.W.3d at 554 (Emphasis added).

hold that a plaintiff must substantially comply, rather than strictly comply, with the requirements of Tenn. Code Ann. § 29-26-121(a)(2)(E).²⁸

In determining whether a plaintiff has substantially complied with a statutory requirement, a reviewing court should consider the extent and significance of the plaintiff's errors and omissions and **whether the defendant was prejudiced by the plaintiff's noncompliance.** Not every non-compliant HIPAA medical authorization will result in prejudice.²⁹

The Tennessee Supreme Court reiterated its holding in *Stevens* in its recent opinion in *Thurmond v. Mid-Cumberland Infectious Disease Consultants, PLC*, --- S.W.3d ----, 2014 WL 1632183 (Tenn. 2014). In *Thurmond*, the Court again held that: (1) “substantial compliance” with the pre-suit notice requirements of Tenn. Code Ann. 29-26-121 will prevent a plaintiff’s health care liability claims from being dismissed; and (2) such claims should not be dismissed unless and until a defendant demonstrates that the non-compliance caused prejudice to the defendant. Therefore, because the Tennessee Defendants can show zero prejudice resulting from the fact that Tennessee Plaintiffs did not send pre-suit health care liability notices to the NECC Defendants, the instant motion must be denied.

E. The Plain Language of Tenn. Code Ann. § 29-26-121 Did Not Require Plaintiffs to Provide the Names and Addresses of Barry Cadden, NECC, and Ameridose in the Notice Letters Sent to the Tennessee Defendants.

Under the plain language of the Tennessee Healthcare Liability Act, Plaintiffs were not required to provide a list containing the names and addresses of Barry Cadden, NECC and Ameridose in the notice letters sent to the Tennessee Defendants. In pertinent part, Tenn. Code Ann. § 29-26-121(a)(2) provides:

(2) The notice shall include:

(D) A list of the name and address of all **providers** being sent a notice;

There are two critical elements in the language of the statute. First, the list called for by the statute need only include the names and addresses of “providers,” i.e., health care providers.

²⁸ *Stevens*, 418 S.W.3d at 556 (Emphasis added).

²⁹ *Id.*

As set forth above, NECC, Barry Cadden and Ameridose are not “health care providers” as that term is used in the Healthcare Liability Act.³⁰ They were acting as drug manufacturers. They maintained no provider/patient relationship with any of the Tennessee Plaintiffs. At the time that plaintiffs received epidural steroid injections administered by the Tennessee Defendants, none of the plaintiffs even knew that NECC, Barry Cadden and Ameridose existed. Therefore, there was no reason to include those parties on a list of “providers being sent the notice.”

Second, the required list need only include: “the name and address of all providers **being sent a notice.**”³¹ The statute expressly recognizes that injured tort victims maintain the prerogative of deciding who to sue and not to sue for health care liability, and the statute conveys the corollary prerogative of deciding to whom to send a pre-suit notice and to whom not to send such a notice. As discussed above, Tennessee Plaintiffs were in no way required to send pre-suit healthcare liability notices to NECC, Barry Cadden and Ameridose because: (1) those plaintiffs could not assert healthcare liability claims against those parties due to the absence of a provider/patient relationship and/or (2) assuming *arguendo* that plaintiffs had viable health care liability claims against NECC, Cadden and Ameridose (which they did not), those defendants expressly waived all pre-suit notice requirements as confirmed by MDL Order No. 6. Therefore, NECC, Cadden and Ameridose were not “being sent a notice” under the statute, and those parties therefore were not required to be listed in the pre-suit notice letters actually sent to the Tennessee Defendants. Plaintiffs complied with the statute.

F. Plaintiffs Were Not Required to Provide HIPAA Releases Permitting Tennessee Defendants to obtain Medical Records from Barry Cadden, NECC, or Ameridose.

The Tennessee Defendants incorrectly assert that Tenn. Code Ann. § 29-26-121(a)(2)(E) required Plaintiffs to provide HIPAA authorizations “permitting Tennessee Defendants to obtain

³⁰ Tenn. Code Ann. § 29-26-101(a)(2).

³¹ Tenn. Code Ann. § 29-26-121(a)(2).

the complete medical records [] from all other providers **who will become defendants in a later-filed action.**³² That, however, is not what the statute says. Because the Tennessee Defendants have either misconstrued Tenn. Code Ann. § 29-26-121(a)(2) or added language that is not contained in the statute, it is important to look at the actual language of the statute. Tenn. Code Ann. § 29-26-121(a)(2) provides:

(2) The notice shall include:

(D) A list of the name and address of all **providers being sent a notice**; and

(E) A HIPAA compliant medical authorization permitting the provider receiving the notice to obtain complete medical records **from each other provider being sent a notice.**

Tenn. Code Ann. § 29-26-121(d)(1) states “[a]ll parties in an action covered by this section shall be entitled to obtain complete copies of the claimant's medical records **from any other provider receiving notice.**”

The statute is consistent. It only refers to providers “being sent a notice” or “receiving notice.” Given that the NECC Defendants were not “being sent a notice,” nor were they “receiving notice” for reasons explained above, Plaintiffs were not required to send HIPAA releases to the Tennessee Defendants authorizing them to obtain medical records from the NECC Defendants.³³

G. The Tennessee Defendants Were Not Deprived of the Opportunity to Obtain Medical Records from the NECC Defendants Because the NECC Defendants Have No Such Records.

The Tennessee Defendants assert that they were deprived of the opportunity to “obtain the patients’ medical records from...Barry Cadden, NECC, or Ameridose...”³⁴ That assertion is

³² Defendants Memorandum, Doc. 898, p. 14.

³³ Several plaintiffs sent blank HIPAA medical releases allowing Defendants to complete the section identifying any health care provider they wished to obtain medical records from if they so desired. If this Court rules that Plaintiffs claims must be dismissed because they were required to send HIPAA releases to the Tennessee Defendants for the NECC Defendants, then this issue no longer becomes a global issue and a case-by-case fact specific analysis must take place.

³⁴ Defendants’ Memorandum, Doc 898, p.15.

untrue. Barry Cadden, NECC, and Ameridose have no medical records regarding Tennessee Plaintiffs. The Tennessee Defendants never provided any individual patient-specific prescriptions to NECC or any of its affiliates. Instead, they sent bulk order forms requesting large shipments of MPA, and they accompanied those bulk order forms with bogus lists containing fictitious names such as “Mickey Mouse.” Thus, the only records possessed by Barry Cadden, NECC and Ameridose are those order forms and lists sent by the Tennessee Defendants, documents which the Tennessee Defendants already have.

Furthermore, no Tennessee Plaintiffs had any direct contact with NECC, Cadden or Ameridose. Accordingly, NECC, Cadden and Ameridose have no medical records regarding Tennessee Plaintiffs. Essentially, the Tennessee Defendants are asking this Court to dismiss Plaintiffs’ claims based upon a purported failure to provide HIPAA releases for medical records that the Tennessee Defendants know do not exist.

H. Given that the Tennessee Defendants Failed to Use the Medical Authorizations that They Received From Certain Plaintiffs, They Cannot Show Prejudice Resulting from a Lack of Medical Authorizations from Other Plaintiffs.

Approximately 141 Tennessee Plaintiffs, represented by 22 law firms, filed suit against the Tennessee Defendants. To the best of the PSC’s knowledge and information, it appears that, of the 141 Tennessee Plaintiffs, only two provided medical authorizations permitting the Tennessee Defendants to request medical records from NECC, Ameridose and Barry Cadden. Those two Plaintiffs are John Charles Sawyers³⁵ and Barbara A. Taylor.³⁶ Counsel for Saint Thomas Clinic has confirmed that they never requested any records regarding Mr. Sawyers from NECC, Ameridose and/or Barry Cadden. In addition, counsel for NECC has confirmed that it never received any requests for records regarding Mr. Sawyers and/or Ms. Taylor. Thus, it

³⁵ Case No. 1:14-cv-10211-RWZ. Mr. Sawyers provided authorizations permitting the respective Tennessee Defendants to obtain records from NECC, Ameridose and Barry Cadden.

³⁶ Case No. 1:13-cv-12673-RWZ . Ms. Taylor provided authorizations permitting the respective Tennessee Defendants to obtain records from NECC and Barry Cadden.

appears that, after receiving medical authorizations from two plaintiffs authorizing the acquisition of medical records from NECC, Ameridose and Cadden, the Tennessee Defendants never used those medical authorizations. They never requested any records from NECC, Ameridose or Cadden regarding either Mr. Sawyers or Ms. Taylor.³⁷

The reason that the Tennessee Defendants did not request medical records from NECC and Barry Cadden is obvious: they know that no such medical records exist. Therefore, the Tennessee Defendants' argument that they were somehow prejudiced by an inability to request medical records from the NECC Defendants is absurd. When given the chance, they did not bother requesting such records. They should not now feign prejudice while asking for the summary dismissal of plaintiffs' claims. The Tennessee Defendants' position is factually incorrect and completely insincere.

I. Plaintiffs' Claims Should Not Be Dismissed If They Substantially Complied With the Statute and Achieved its Purposes.

Before this Court can dismiss any plaintiff's claims, it must conduct a case specific inquiry about whether the plaintiff substantially complied with the requirements of Tenn. Code Ann. § 29-26-121(a). As explained by the Tennessee Supreme Court in *Stevens*, the purposes of the pre-suit notice requirements articulated in Tenn. Code Ann. § 29-26-121(a) include: (1) requiring plaintiffs to notify health care defendants of impending litigation before it occurs, (2) facilitating settlement negotiations by informing target defendants of upcoming litigation so that pre-suit settlements can occur, and (3) allowing target health care defendants to investigate

³⁷ Counsel for Saint Thomas Clinic has confirmed that his law firm never requested records from NECC and/or Barry Cadden regarding John Charles Sawyers. In addition, Counsel for Saint Thomas Clinic has stated that he would likewise determine the same for Barbara A. Taylor, but he has not reported back to plaintiffs' counsel. Counsel for NECC has confirmed that it never received any requests for records regarding either Mr. Sawyers or Ms. Taylor.

potential claims by gathering medical records from other defendants being sent the notice.³⁸ In the present litigation, all of those purposes were achieved by numerous Tennessee plaintiffs.

In fact, the chart which is the first exhibit to the Tennessee Defendant's motion (Doc. 770-1) reveals numerous plaintiffs whose **only** purported violation of the subject statute is an alleged failure to include the NECC Defendants in the pre-suit notice letters and medical authorizations that were in fact sent to the Tennessee Defendants. In other words, by the Tennessee Defendants' own implied admission, numerous plaintiffs, without question, complied with the letter and spirit of Tenn. Code Ann. §§ 29-26-121 and -122 by flawlessly accomplishing the following:

- Sending a pre-suit notice letter via Certified U. S. Mail, Return Receipt Requested to the Tennessee Defendants more than 60 days before filing suit;
- Including in the pre-suit notice the patient's full name, date of birth, the identity of the patient's counsel, as well as all other information required by the statute;
- Providing the Tennessee Defendants with a list of all Tennessee health care providers who were likewise receiving a pre-suit notice;
- Enclosing with the pre-suit notice a medical authorization that complied with HIPAA in every respect;
- Having the patient's claims reviewed by a qualified expert before suit was filed;
- Requiring the reviewing expert to sign a written statement certifying the merits of the patient's claims before suit was filed;
- Filing with the Complaint an affidavit confirming that the pre-suit notice letters were duly sent;
- Attaching a copy of the pre-suit notice letters and Certificates of Mailing to the Complaint; and
- Attaching to the Complaint a certificate from plaintiff's counsel certifying that the required pre-suit expert review was obtained.

³⁸ *Stevens*, 418 S.W.3d at 554.

In spite of the fact that numerous plaintiffs accomplished each of those steps without reproach, the Tennessee Defendants nevertheless claim that even those plaintiffs' claims should be summarily dismissed. Such a result would be contrary to the substantial compliance and actual prejudice requirements articulated in *Stevens*, 418 S.W.3d at 554-556, and it would violate basic precepts of justice.

This Court should not summarily dismiss any plaintiff's claim before conducting a careful review of that particular plaintiff's pleadings in order to determine whether she substantially complied with the statute and whether the Defendants suffered any actual prejudice. In addition, no case should be dismissed before the injured plaintiff is given an opportunity to be heard on the issue of substantial compliance. Therefore, the subject motion must be denied.

J. The Assertion That Complaints Should Be Dismissed Based upon a Patient's Middle Name not being Included in the Notice Letter is Completely Without Merit.

The Tennessee Defendants seek dismissal of several cases based upon the hyper-technical point that, perhaps, not all Plaintiffs provided "full names"³⁹ of the patient who received the tainted injection.⁴⁰ There is nothing which actually supports the Defendants' request. There is quite a bit which indicates that it should be denied.

First, the Tennessee Supreme Court has clearly ruled that a party's procedural error must result in actual prejudice to an opposing party before that procedural error results in dismissal.⁴¹ Plaintiffs do not concede that any procedural error occurred. However, even if a procedural error occurred on some of the notices, the Tennessee Defendants offer no proof that they were actually prejudiced.

³⁹ Defendants do not define what they mean by "full name." Some notices contain first, middle and last names. Other notices contain first name, middle initial and last name. Other notices may contain various other differences. Undoubtedly, some patients do not have a middle name. If the Court determines that the first name, middle initial and last name (or some similar variable) does not substantially comply with the statute and that dismissal is required, then a case by case analysis must be performed.

⁴⁰ Defendants' Memorandum, Doc. 898, p. 15.

⁴¹ *Stevens*, 418 S.W.3d at 554.

The Defendants cannot show actual prejudice merely because a plaintiff omitted her middle name from a notice. One purpose of the pre-suit notice requirement is to provide potential defendants with the ability to identify which patients intend to sue them and identify counsel for those patients.⁴² Because the Defendants cannot show that they experienced any difficulty in that regard, there is no reason to summarily dismiss anyone's claims.

The Defendants cannot show actual prejudice because the subject patients were the Defendants' *own patients* whom the Defendants had previously identified and notified of the fungal meningitis outbreak. In other words, before any injured plaintiffs sent any health care liability pre-suit notices, the Tennessee Department of Health and the CDC required Saint Thomas Clinic to identify and notify those persons who received contaminated steroid injections. Therefore, the Defendants cannot claim that they were unable to ascertain which patients were planning to file claims against them. They already knew exactly who those persons were because the government previously required the Defendants to identify those persons. Therefore, the suggestion that the Tennessee Defendants were somehow prejudiced by the fact that a particular patient did not include her middle name on a pre-suit notice letter is both false and ludicrous.

Second, in interpreting a Tennessee statute, this Court essentially acts as a Tennessee court. Tennessee courts are required to interpret statutes in a manner that makes "practical sense."⁴³ It cannot be said to make "practical sense" to dismiss meritorious claims (as established by the certificate of good faith filed with the Complaint) based upon the hyper technical omission that someone did not supply a middle name on a notice form.

Third, according to the Tennessee Supreme Court, a middle name is not required in order for a name to be legally effective and complete. In the case of *Dunn v. Palermo*, 522 S.W.2d

⁴² *Stevens*, 418 S.W.3d at 553.

⁴³ *Powell v. Cmty. Health Sys., Inc.*, 312 S.W.3d 496, 508 (Tenn. 2010)(quoting *N.C. & St. L. Ry.. vs. Carroll County*, 12 Tenn. App. 380, 386 (1930)).

679 (Tenn. 1975), the Tennessee Supreme Court stated: “So long as a person’s name remains constant and consistent, and unless and until changed in the prescribed manner, and absent any fraudulent or legally impermissible intent, the State has no legitimate concern. We hold that appellee’s legal name is Rosary T. Palermo.”⁴⁴ In other words, a middle name is not necessary for a name to be legal.

Fourth, the practice of various government institutions, such as the Internal Revenue Service [“IRS”], indicates that a middle name is not required in order for a name to be legally sufficient. The IRS obviously considers less than a “full name” sufficient given that it specifies “last name, first name, and middle initial” on its form 1040. (Copy attached as Exhibit 3).

Finally, there is the practical matter of how the Tennessee providers dealt with the patient. If they accepted a person as a patient and accepted her money for treatment based upon less than a “full name,” they can hardly be heard to suggest that their injured patient’s claims should be dismissed summarily simply because she did not include a middle name in a pre-suit notice form.

K. If This Court Determines That a Violation of Tenn. Code Ann. § 29-26-121 has Occurred, it Must Conduct A Case Specific Hearing about Whether Extraordinary Cause Exists to Excuse the Violation.

Before this Court dismisses any claim based upon a violation of Tenn. Code Ann. § 29-26-121, it must determine whether extraordinary cause exists for excusing the subject violation.⁴⁵ Such a determination can only be made after the Court conducts a case specific inquiry affording individual plaintiffs with the opportunity to be heard regarding mitigating factors, circumstances surrounding the particular violation, and why their claims should not be dismissed.⁴⁶ Therefore, if this Court determines that any violation of Tenn. Code Ann. § 29-26-121 or Tenn. Code Ann. § 29-26-122 occurred, the proper procedure is not to throw out an injured plaintiff’s case

⁴⁴ *Dunn* at p. 689.

⁴⁵ See Tenn. Code Ann. § 29-26-121(b) and Tenn. Code Ann. § 29-26-122(a).

⁴⁶ See generally *Myers*, 382 S.W. 3d at 307 and *Stevens*, 418 S.W.3d at 556-557.

automatically. The plaintiff must be given the opportunity to be heard on the issue of extraordinary cause. Accordingly, this Court should not dismiss any claims summarily without affording individual plaintiffs the opportunity to be heard on the circumstances surrounding their particular case.

CONCLUSION

For the forgoing reasons, the Tennessee Defendants' Motion to Dismiss (Doc. 770) should be denied as to all issues discussed in this response.

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Respectfully submitted,

/s/ George Nolan

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Plaintiffs' Steering Committee

CERTIFICATE OF SERVICE

I, George Nolan, hereby certify that I caused a copy of the foregoing to be filed electronically via the Court's electronic filing system. Those attorneys who are registered with the Court's electronic filing system may access these filings through the Court's system, and notice of these filings will be sent to these parties by operation of the Court's electronic filing system.

/s/ George Nolan
George Nolan